UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

IN RE SPERO THERAPEUTICS, INC., SECURITIES LITIGATION	**MEMORANDUM AND ORDER** 22-CV-3125 (LDH) (MMH)

LASHANN DEARCY HALL, United States District Judge:

Kashif Memon, Nabil Saad, and Richard Germond ("Plaintiffs"), individually and on behalf of all persons who purchased or otherwise acquired Spero Therapeutics common stock between September 8, 2020, and May 3, 2022 (the "Class Period"), bring the instant action against Spero Therapeutics, Inc. ("Spero"), Ankit Mahadevia, and Satyavrat Shukla (together with Spero, "Defendants"), alleging violations of Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 ("Exchange Act"). Defendants move pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure to dismiss the Complaint in its entirety.

I. BACKGROUND[1]

A. Regulatory Framework for the Approval of a New Drug

Under the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration ("FDA") is tasked with ensuring that drugs and devices are safe and effective for their intended uses. 21 U.S.C. §§ 351–360. Companies seeking to commence a clinical investigation of a new drug must submit an Investigational New Drug Application ("IND") to the FDA. 21 C.F.R. §

[1] The following facts are taken from Plaintiff's amended complaint (ECF No. 20) and, unless otherwise indicated, are assumed to be true for the purposes of this memorandum and order.

312.20. A clinical investigation of a new drug is generally divided into three phases. *See* 21 C.F.R. § 312.21. Phase 1 includes the initial introduction of the drug into humans, and generally involves 20 to 80 patients. 21 C.F.R. § 312.21(a). Phase 2 includes "controlled clinical studies conducted to evaluate the effectiveness of the drug for a particular indication . . . in patients with the disease or condition under study" and generally involves no more than several hundred subjects. 21 C.F.R. § 312.21(b). Phase 3 includes expanded controlled and uncontrolled trials "performed after preliminary evidence suggesting effectiveness of the drug has been obtained" and usually includes several hundred to several thousand subjects. 21 C.F.R. § 312.21(c).

After the three clinical investigation phases are complete, but prior to filing a New Drug Application ("NDA"), a sponsoring company meets with the FDA to exchange information about the proposed drug marketing application. 21 C.F.R. § 312.47. This pre-NDA meeting provides an opportunity for the sponsoring company to: (1) "uncover any major unresolved problems," (2) "identify those studies that the sponsor is relying on as adequate and well-controlled to establish the drug's effectiveness," (3) "identify the status of ongoing or needed studies adequate to assess pediatric safety and effectiveness," (4) "acquaint FDA reviewers with the general information to be submitted in the marketing application (including technical information)," (5) "discuss appropriate methods for statistical analysis of the data," and [6] "discuss the best approach to the presentation and formatting of data in the marketing application." 21 C.F.R. § 312.47(b)(2).

Once a pre-NDA meeting is held, the sponsoring company may formally request FDA approval of a drug for marketing in the United States through submission of an NDA. 21 C.F.R. § 314.50. The NDA includes all animal and human data and analyses of the data, as well as information about how the drug behaves in the body and how it is manufactured. *Id.* The FDA

has 60 days after an NDA is received to decide whether to file the NDA for review. 21 C.F.R. § 314.101(a)(1). If the FDA determines that the filing of the NDA should be refused, the FDA will notify the applicant in writing and state the reason for the refusal. 21 C.F.R. § 314.101(a)(3). At that time, an applicant whose filing of an NDA was refused for regulatory deficiencies is provided an opportunity to amend its application and resubmit it to the FDA for review. *Id.* Where the FDA finds no basis to refuse the filing of an NDA, the FDA will file the NDA for substantive review. 21 C.F.R. § 314.101(a)(2). Once the review is complete, the FDA will either approve the NDA or issue a complete response letter rejecting the application. 21 C.F.R. § 314.110(a). Approvals are not granted, however, until after the FDA "determines that the drug meets the statutory standards for safety and effectiveness, manufacturing and controls, and labeling[.]" 21 C.F.R. § 314.105(c).

B. Spero's Development of THBr

Spero is a biopharmaceutical company founded in 2013 that focuses on identifying, developing, and commercializing treatments for multi-drug resistant bacterial infections and rare diseases in the U.S. (Am. Compl. ¶ 35., ECF No. 20.) During the Class Period, Spero sought FDA approval for an anti-bacterial pill called tebipenem pivoxil hydrobromide (hereinafter "THBr"), which was intended to treat complicated urinary tract infections ("cUTI").[2] (*Id.* ¶¶ 35, 36.) Because the treatment of cUTIs typically requires hospitalization and intravenous medication, the development of an orally administered and more-cost-effective treatment would be significant. (*Id.* ¶ 34.)

On October 20, 2017, Spero announced the initiation of a Phase 1 safety, tolerability, and pharmacokinetics study of THBr. (*Id.* ¶ 39.) In its announcement, Spero shared that the FDA

[2] A cUTI occurs "when a patient presents with any functional, metabolic, or anatomical condition that may increase the risk of treatment failure or adverse outcomes." (*Id.* ¶ 32.)

had designated THBr as a Qualified Infectious Disease Product for cUTIs. (*Id.*) "This designation incentivizes manufacturers of new antibiotic treatments by offering them benefits including FDA priority review and eligibility for additional market exclusivity." (*Id.*) Three days later, Spero launched its IPO, raising $83.6 million in gross proceeds. (*Id.* ¶ 40.)

Upon the FDA's acceptance of Spero's IND for THBr on February 4, 2019, Spero initiated patient enrollment in a Phase 3 clinical trial (the "ADAPT-PO Trial" or the "Trial"). (*Id.* ¶ 41.) On March 29, 2019, Spero announced that the FDA granted THBr a Fast Track Designation, which expedites the review of drugs intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs. (*Id.*) The designation also allowed Spero to interact with the FDA more frequently regarding the development of THBr and provided for rolling review of its NDA. (*Id.*)

At some point during Phase 3 of the ADAPT-PO Trial, the Trial's data review committee recommended that Spero enroll 1,450 patients, the maximum enrollment for which the trial was eligible. (*Id.* ¶ 168.) The data review committee recommended the maximum sample size to "ensure adequate power for measurement of the primary endpoint," which is the basis for determining whether a treatment is effective.[3] At some point during Phase 3 of the Trial, the FDA concluded that gram-positive[4] patients, who comprised approximately 15% of the Trial's patients, were not part of the evaluable patient population. (*Id.* ¶¶ 54, 160.) The exclusion of

[3] The Court takes judicial notice that a "primary endpoint" is the main result measured at the end of a study to assess whether a given treatment worked (*e.g.*, the number of deaths or the difference in survival between the treatment group and the control group). A primary endpoint is determined before a study begins. *See* National Institute of Health National Cancer Institute Dictionaries, https://www.cancer.gov/publications/dictionaries/cancer-terms/def/primary-endpoint (last visited September 20, 2024).

[4] The Court takes judicial notice that bacteria are classified as either gram-positive or gram-negative, subject to their response to a staining procedure developed during the 19th century by bacteriologist Christian Gram. *See* Silhavy, Kahne, and Walker, *The Bacterial Cell Envelope*, v.2(5) Cold Spring Harbor Perspectives in Biology (May 2010).

gram-positive patients meant that the Trial could not meet the required non-inferiority margin[5] of -12.5% against its already approved comparator, IV ertapenem. (*Id.*) By May 2020, Spero decided to proceed with 1,372 patients enrolled in the Trial. (*Id.* ¶ 42.)

By March 2021, Defendants publicly disclosed that at least one pre-NDA meeting with the FDA had occurred, during which they discussed "the format and content of the planned data package" that would accompany the THBr NDA. (*Id.* ¶ 172.) On September 29, 2021, during a presentation at the 2021 Cantor Virtual Global Healthcare Conference, Defendant Mahadevia stated that the data collected in the ADAPT-PO Trial was proper for approval based on meetings with the FDA. (*Id.* ¶ 109.) According to a confidential witness,[6] starting in December 2021, Spero began to receive at least weekly comments from the FDA regarding the NDA, a noticeable uptick from the earlier pace of interactions. (*Id*. ¶ 173.) The FDA's frequent feedback continued through February 2022. (*Id.*)

Throughout the Class Period, Defendants issued several public statements regarding THBr's statistical non-inferiority against IV ertapenem. For example, on September 8, 2020, Spero provided an update on the Trial in a press release attached to its publicly filed Form 10-K, stating that THBr was "well tolerated" and had a similar safety profile as the already-approved IV drug, ertapenem. (*Id.* ¶ 43.) The update also explained that THBr, as compared to ertapenem, met the necessary threshold of a -12.5% non-inferiority margin. (*Id.*) Plaintiffs allege that Defendant issued the same or similar statements regarding THBr's statistical non-inferiority throughout the Class Period in several public SEC filings (*e.g., id.* ¶¶ 59(a), 87(c),)

[5] The Court takes judicial notice that "noninferiority trials are used to assess whether the effect of a new drug is not worse than an active comparator by more than a noninferiority margin. If the difference between the new drug and the active comparator does not exceed this prespecified margin, noninferiority can be concluded." *See* Althunian, de Boer, Groenwold, and Klunger, *Defining the noninferiority margin and analysing noninferiority: An overview*, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5510081/ (last visited September 19, 2024).
[6] The confidential witness ("CW2") was an Associate Director in Spero's Regulatory Affairs Department. (*Id.* ¶ 173.)

and press releases (*e.g., id.* ¶¶ 59(c), 69, 71(a)), during investor presentations and earnings calls (*e.g., id.* ¶¶ 59(b), 63, 123), and at public conferences (*e.g., id.* ¶¶ 77, 89, 103).

Defendants also issued numerous statements regarding the prospect of THBr's approval and commercial launch given its performance during the Trial. For example, on August 5, 2021, in a press release attached to a Form 10-K filed that day, Spero announced that it had achieved "key milestones which ha[d] [it] well-positioned for future success as [it] work[ed] to submit the [THBr] NDA." (*Id.* ¶ 101(a).) The press release further stated that Spero's primary focus was "advancing [THBr] towards an NDA filing" in 2021. (*Id.*) And during an August 5, 2021 earnings call with analysts and investors regarding Q3 2021 financial results, Defendant Mahadevia, Spero's CEO, stated that Spero anticipated a "THBr commercial launch in the second half 2022." (*Id*. ¶ 113(b).). Mahadevia also stated that Spero had achieved "key milestones" toward that goal, including the submission of the NDA filing, and that "[p]revious FDA interactions . . . support[ed] [Spero's] efforts to advance [THBr] towards commercialization." (*Id.*) Defendants issued the same or similar statements regarding the THBr NDA filing and potential commercial launch in public filings (*e.g., id.* ¶¶ 95, 125(a), 144(b)), press releases (*e.g., id.* ¶¶ 101, 111, 119), and on earnings calls (*e.g., id.* ¶¶ 113(b), 125(b)) during the Class Period.

On March 31, 2022, Spero issued an "after-hours" press release announcing that the FDA "ha[d] notified Spero that, as part of its ongoing review of Spero's New Drug Application (NDA) for [THBr], it ha[d] identified deficiencies that preclude discussion of labeling and post-marketing requirements/commitments at this time." (*Id.* ¶ 156.) Spero did not disclose the deficiencies in the March 2022 announcement. Later, on May 3, 2022, in a press release attached to a Form 8-K filed that day, Spero announced that it would immediately defer plans for

the commercial launch of THBr based on the FDA's feedback during a Late Cycle Meeting (LCM)[7] regarding the NDA. (*Id.* ¶ 159.) The press release stated further that although "the review [was] still ongoing and the FDA ha[d] not yet made any final determination regarding approvability, the discussion suggested that the data package may be insufficient to support approval during this review cycle." (*Id.*) As a result of the separate analysis, the FDA found that the "pre-specified [NI] margin of -12.5% was not met."[8] (*Id.*) Spero also announced that it was undertaking a reduction in its workforce by approximately 75% and a restructuring of its operations to reduce operating costs and reallocate resources. (*Id.*)[9]

C. Individual Defendants

Both Defendants Mahadevia, Spero's CEO, and Shukla, Spero's CFO, received increases in their executive compensation during the Class Period. (*Id.* ¶ 181.) Although Spero's annual salary increases became effective on February 1 each year, "the Individual Defendant[10] received an additional salary increase on July 1, 2021." (*Id.* ¶ 182.) Mahadevia's 2021 compensation

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[7] The Court takes judicial notice that a Late Cycle Meeting is a meeting held with NDA applicants to discuss the status of the review of the application late in the review cycle. This meeting is not intended to discuss the pending regulatory decision on the application. *See* SOPP 8401: Administrative Processing of Original Biologics License Applications (BLA) and New Drug Applications (NDA), https://www.fda.gov/media/85659/download (last visited September 19, 2024.)

[8] According to Oppenheimer, an analyst firm, the FDA "excluded patients infected with a pathogen called Enterococcus, a gram-positive pathogen which usually accounts for 10%-15% of cUTIs and accounted for 15% of the patients in the ADAPT-PO Trial with cUTI." (*Id.* ¶ 160.) Removing those patients reduced the population from 868 to 734 patients. (*Id.*) Oppenheimer reported "FDA's exclusion of Enterococcus was a surprise to us." And, an Evercore analyst reported that "it's hard to know what exactly the [FDA] is thinking." (*Id.* ¶ 162.)

[9] Plaintiffs also point to the allegations of several confidential witnesses ("CWs") regarding Defendants' actions between February and May 2022. CW1 was the Director of Clinical Data Management at Spero from February 2019 through February 2022 and was responsible for charge of data management Trial. (*Id.* ¶ 25.) CW1" found it "odd" that Spero let CW1 quit "without any effort to retain CW1 . . . during the late stages of the NDA process." (*Id.* ¶ 174(a).) Multiple other confidential witnesses ("CW3," "CW4," and "CW6") "described a lack of candor by the Individual Defendants when they held a company-wide conference call in March 2022 to announce that the FDA had identified deficiencies in the [THBr] NDA." (*Id.* ¶ 174(b).) Further, CW2 reported that while preparing for the Late Cycle Meeting, the VP of Regulatory Affairs gave an instruction from the 'leadership team' that CW2 restrict access to all the FDA submission documents for THBr within the company's computer system to a tight circle of personnel. (*Id.* ¶ 174(c).) CW3, CW4, and CW6 each expressed "surprise[]" at the large layoff, including at "how fast Spero shut down most operations and officially terminated so many employees" so quickly. (*Id.* ¶ 174(d).)

[10] It is unclear whether Mahadevia or Shukla, or both, received this increase.

increased $80,000 from his 2020 salary of $540,000 to $620,000, with an increase in bonus eligibility equivalent to an extra 10% of his base salary." (*Id.* ¶ 183.) Mahadevia's salary raises were significantly lower in previous years, at $35,000 in 2019, and $40,000 in 2020. (*Id.*) Between September 2020 and December 2021, Mahadevia sold $471,518 of Spero stock and exercised $193,361 of stock options for a net gain of $278,157. (*Id.* ¶ 177.) These transactions were 163% larger than the $169,908 in net gains from the pre-Class Period stock sales. (*Id.* ¶ 178.) Shukla received an off-schedule $35,000 raise in July 2021, from $425,000 to $460,000 with a target bonus opportunity of 40% of his base salary. (*Id.* ¶ 184.) Shukla received this bonus opportunity after working for the company for only five months. (*Id.*) In addition, Shukla's employment agreement contained provisions "entitling him to lavish severance payments should Spero terminate him without cause or should he terminate the contract 'for good reason.'" (*Id.*)

II. STANDARD OF REVIEW

To withstand a Rule 12(b)(6) motion to dismiss, a complaint "must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). A claim is facially plausible when the alleged facts allow the court to draw a "reasonable inference" of a defendant's liability for the alleged misconduct. *Id*. While this standard requires more than a "sheer possibility" of a defendant's liability, *id.*, "[i]t is not the Court's function to weigh the evidence that might be presented at trial" on a motion to dismiss. *Morris v. Northrop Grumman Corp.*, 37 F. Supp. 2d 556, 565 (E.D.N.Y. 1999). Instead, "the Court must merely determine whether the complaint itself is legally sufficient, and, in doing so, it is well settled that the Court must accept the factual allegations of the complaint as true." *Id.*

(citations omitted). Moreover, "Rule 12(b)(6) does not give the district court authority to consider matters outside the pleadings[.]" *LaBounty v. Adler*, 933 F.2d 121, 123 (2d Cir. 1991). And it is "generally improper for the court to consider factual averments contained in affidavits on a Rule 12(b)(6) motion." *Amadei v. Nielsen*, 348 F. Supp. 3d 145, 155 (E.D.N.Y. 2018) (quoting *Fonte v. Bd. Of Managers of Cont'l Towers Condo.*, 848 F.2d 24, 25 (2d Cir. 1988)).

Additionally, claims alleging fraud require a plaintiff to "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). A plaintiff seeking to avoid dismissal of a securities complaint must also satisfy the pleading requirements included in the Private Securities Litigation Reform Act ("PSLRA"). *See S. Cherry St. LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 110 (2d Cir. 2009). Congress enacted the PSLRA in 1995 in part "[a]s a check against abusive litigation by private parties." *Id.* at 111. To accomplish this goal, Section 21D(b)(2) of the PSLRA provides that "the complaint shall, with respect to each act or omission alleged to violate this chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required statement of mind." *Id.*

III. DISCUSSION

A. Exchange Act Section 10(b) and Rule 10b−5

Section 10(b) of the Securities Exchange Act of 1934 and Rule 10b–5 promulgated thereunder prohibit fraudulent activities in connection with securities transactions. Specifically, Section 10(b) makes it unlawful "[t]o use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance in contravention of such rules and regulations as the Commission may prescribe as necessary or appropriate in the public interest or for the protection of investors." 15 U.S.C. § 78j(b). Likewise, Rule 10b–5 specifies that it is unlawful "[t]o make any untrue statement of a material fact or to omit to state a material

fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not misleading[.]" 17 C.F.R. § 240.10b–5.

"To state a claim on which relief can be granted under Section 10(b) and Rule 10b–5, a plaintiff must plead, *inter alia*, that in connection with the purchase or sale of securities, the defendant made a false representation as to a material fact, or omitted material information, and acted with scienter." *S. Cherry St., LLC*, 573 F.3d at 108. Scienter is "a mental state embracing intent to deceive, manipulate, or defraud," *In re Alkermes Pub. Ltd. Co. Sec. Litig.*, which is sufficiently plead by "alleging facts that demonstrate that a defendant had motive and opportunity to commit fraud, or a strong showing of reckless disregard for the truth." 523 F. Supp. 3d 283, 292 (E.D.N.Y. 2021) (citing *ECA, Local 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009)). Scienter allegations must be read holistically and "need not be irrefutable, *i.e.*, of the 'smoking-gun' genre.'" *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007). Still, the inference of scienter must be at least as compelling as non-culpable allegations, and when they are, "the tie … goes to the plaintiff." *See Okla. Firefighters Pension & Ret. Sys. v. Lexmark Int'l, Inc.*, 367 F. Supp. 3d 16, 39 (S.D.N.Y. 2019) (citation omitted). To sufficiently allege scienter, Plaintiffs must plead facts "(1) showing that the defendants had both motive and opportunity to commit the fraud or (2) constituting strong circumstantial evidence of conscious misbehavior or recklessness." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.,* 493 F.3d 87, 99 (2d Cir. 2007). Here, Defendants argue that Plaintiffs' claims must be dismissed because Plaintiffs fail to sufficiently allege scienter. The Court agrees.

1. Recklessness

The Second Circuit defines recklessness as the "state of mind approximating actual intent, and not merely a heightened form of negligence." 573 F.3d at 109. Recklessness is demonstrated by conduct that is "at the least . . . highly unreasonable and . . . represents an extreme departure from the standards of ordinary care to the extent that the danger was either known to the defendant or so obvious that the defendant must have been aware of it . . . ." *Id.* Because there is no affirmative duty to disclose the FDA's interim feedback, "the mere allegation that defendants failed to disclose relevant information does not in and of itself constitute strong evidence that they did so with scienter." *In re Alkermes Pub. Ltd. Co. Sec. Litig.*, 523 F. Supp. 3d at 292 (quoting *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 534 (S.D.N.Y. 2015)). Critically, "[s]cienter arises in this context, where 'the management knows that certain facts will necessarily prevent regulatory approval . . . and conceals those facts from the investing public.'" *Id.* at 293 (quoting *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d at 529). Thus, the threshold for scienter is "near certainty" that a drug will not be approved. *In re Chembio Diagnostics, Inc. Sec. Litig.*, 616 F. Supp. 3d 192, 199 (E.D.N.Y. 2022).

Plaintiffs' primary theory of Defendants' purported recklessness relies heavily upon Defendants' enrollment of 1,372 patients for the ADAPT-PO Trial rather than the 1,450 patients recommended by the Trial's data review committee. (Pls.' Mem. in Opp'n to Defs.' Mot. to Dismiss ("Pls.' Opp'n") at 5, ECF No. 36.) Indeed, Plaintiffs dedicate no fewer than 33 paragraphs to reiterating that the Trial lacked a sufficiently evaluable patient population. (*See, e.g.,* Am. Compl. ¶¶ 60, 62, 64).[11] But, as Defendants argue, Plaintiffs mischaracterize the article on which they rely to argue that the alleged under-enrollment evinces Defendants'

[11] *See also id.* ¶¶ 66, 68, 70, 72, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94, 96, 98, 100, 102, 104, 106, 108, 110, 112, 114, 116, 118, 120, 122, 124.

recklessness. (Defs.' Mem. Supp. Mot. to Dismiss ("Defs.' Mem.") at 22, ECF No. 34.) While it is true that the data review committee ultimately recommended the maximum enrollment of 1,450 patients, the article makes clear that Spero's decision to proceed with fewer patients was made "*in consultation with the FDA*" to navigate operational challenges presented by the COVID-19 pandemic. (Sylvia Decl., Ex. G at 1329, ECF No. 35) (emphasis added). The Court declines to view the reduced patient population as "highly unreasonable" when the decision was made with the FDA's guidance. And Plaintiffs plead no facts suggesting that Defendants knew or should have known that the enrollment would present an issue later. Accordingly, Defendants' decision to proceed with 1,372 patients enrolled in the Trial does not support a finding of scienter.

Plaintiffs also argue that Defendants' heightened access to the FDA under the Fast Track Designation supports an inference that Defendants recklessly disregarded "red flags" that the drug would not be approved due to trial data deficiencies. (Pls.' Opp'n at 6.) Specifically, Plaintiffs assert that the FDA raised its concerns regarding the inclusion of gram-positive patients during numerous meetings with Defendant between September 2020 and the end of 2021, and "usually high scrutiny between December 2021 and February 2022." (Pls.' Opp'n at 24.) The Court is unconvinced. There is not a single allegation in the 174-page complaint that establishes the content of any meeting between Spero and the FDA regarding the patient population. Plaintiffs plead that six confidential witnesses describe a "fever pitch" of interactions between Spero and the FDA regarding the clinical data. (Am. Compl. ¶ 6; Pls.' Opp'n at 6.) But a heightened frequency of interactions between Spero and the FDA, which Plaintiffs concede is typical of Fast Track Designation (Am. Compl. ¶ 171), provides the Court no insight into what, if anything, the FDA said about the inclusion of gram-positive patients.

Not even the allegations of the confidential witnesses who were directly involved in communications with the FDA regarding the NDA, shed any light on specific concerns that the FDA may have had regarding the patient population. (Am. Compl. ¶¶ 49, 52.) At most, Plaintiffs plead that "[f]rom what CW5 understood, the FDA's thinking was that gram-positive bacteria are resistant to IV ertapenem, which would justify FDA's excluding gram-positive bacteria from the trial." (*Id.* ¶ 52.) But this conjecture as to the FDA's "thinking" does not amount to a specific concern that the agency communicated to Spero. Under these circumstances, the Court cannot conclude that the frequent meetings were a red flag or otherwise made non-approval a near certainty. Accordingly, Spero's heightened access to the FDA under the Fast Track Designation does not support an inference of scienter.

Finally, Plaintiffs argue that Defendants' "highly suspicious" conduct between February and May 2022 before and during the corrective disclosures evinces scienter. (Pls.' Opp'n at 13.) The Court disagrees. Plaintiffs plead that four instances of conduct were "highly suspicious." But none of Plaintiffs proposed inferences of scienter are "cogent [or] at least as compelling as the opposing inference[s] of nonfraudulent intent." *ECA, Loc. 134 IBEW Joint Pension Tr. of Chicago v. JP Morgan Chase Co.*, 553 F.3d 187, 198 (2d Cir. 2009). First, Plaintiffs point to the fact that Defendants "let" CW2, Director of Clinical Data Management, quit during the late stages of the NDA process in February 2022. (Am. Compl. ¶ 48.) But as Defendants argue, nothing in the FAC suggests that CW2 was not an employee at will or that CW2 was so indispensable that the Company should have expended exceptional effort to retain him or her. (Defs.' Mem. at 16.) Second, Plaintiffs allege that, during a March 2022 company-wide conference call, Defendants refused to disclose to employees the details of the deficiencies that the FDA had identified. (*Id.* ¶ 51.) However, as Defendants note, Plaintiffs concede that both

CW2 and CW5, a "high-level employee" in Spero's commercial division, were "brought into the tent" of the Company's interactions with the FDA. (Defs.' Mem at 16.) And Plaintiffs plead no facts suggesting that Defendants were obligated to provide the entire company a detailed update as to the status of the trial. Third, Plaintiffs point to Defendants' alleged direction to CW2 in early April 2022 to "make all the FDA submission documents for [THBr] confidential in the company's system to limit access to just a C-suite executive, three people in regulatory affairs (including CW2), [and] two people in [Chemistry, Manufacturing, and Control]." (Am. Compl. ¶¶ 49, 53.) And finally, Plaintiffs point to the speed with which Defendants conducted a mass layoff in May 2022 immediately after the Late Cycle Meeting with the FDA. (Am. Compl. ¶ 49.) As Plaintiffs' argument goes, these facts suggest that Defendants were aware that the drug would not be approved on their anticipated timeline and began insulating information related to the Trial to prepare for a mass layoff. (Pls.' Opp'n at 17.) However, the more compelling justification is that Defendants were aware of some risk that the drug would not be approved, but "some" risk is a far cry from near certainty. As Defendants point out, the decision to conduct a layoff was executed in May 2022, *after* the FDA made its determination concerning gram-positive patients. (Defs.' Mem. at 16.) This timing demonstrates that Defendants engaged in such conduct only when it was a near certainty that the drug would not be approved. Thus, at most, these facts show that Defendants were aware of a risk, not of a near certainty. *See In re Chembio*, 616 F. Supp. 3d at 198 (denying reconsideration of dismissal of securities complaint where "plaintiffs here, by contrast, have pleaded that after the April 29 call, the *Chembio* defendants were aware merely of an increased *risk* of revocation . . . not that there was a near certainty that the Test would be revoked.").

2. Motive and Opportunity

Plaintiffs argue that insider transactions, increased executive compensation, public offerings, and unearned government windfall payments support a finding of scienter through motive and opportunity. (Pls.' Opp'n at 25–28.) The Court disagrees. "[T]o raise a strong inference of scienter through 'motive and opportunity' to defraud[,] [p]laintiff [] must allege that [defendants] 'benefited in some concrete and personal way from the purported fraud.'" *ECA*, 553 F.3d at 198 (citing *Novak v. Kasaks*, 216 F.3d 300, 307–08 (2d Cir. 2000). Here, Plaintiffs fail to adduce any facts connecting these alleged transactions and financial benefits to Defendants' purported awareness of the Trial's deficiencies.

Plaintiffs allege, in conclusory fashion, that the timing of insider transactions and increases in executive compensation support an inference of scienter through motive and opportunity. (Pls.' Opp'n at 6.) But Plaintiffs' allegations do not support this argument. Indeed, none of the alleged insider stock transactions were executed between March and May 2022, the period during which it would have been arguably "unusual" for an insider to make trades, given Defendants' receipt of the deficiency letter. *See In re Aegean Marine Petroleum Network, Inc. Sec. Litig.*, 529 F. Supp. 3d 111, 173 (S.D.N.Y. 2021) ("Unusual insider sales at the time of the alleged withholding of negative corporate news may permit an inference of bad faith and scienter." (quotation marks and citation omitted)). Instead, Plaintiffs plead 12 such transactions in 2020, three in 2021, and only one in February 2022. (Am. Compl. ¶ 177.) The same is true of the alleged increases in executive compensation. Where executive compensation has been found sufficient to plead scienter, the compensation was tied to the alleged fraud. *See, e.g., In re Vivendi*, 381 F. Supp. 2d 158, 185 (S.D.N.Y. 2003) (holding an allegation that defendant received bonus of more than $3 million sufficient to plead scienter where plaintiff also pleaded

that defendant "had an even greater motive for inflating the appearance of Vivendi's financial performance, from which he derived a specific concrete benefit by virtue of the false statements and wrongful nondisclosures alleged.") Here, Plaintiffs allege that "suspicious" pay increases took place in 2021, well before Spero's receipt of the deficiency letter. (Pls.' Opp'n at 13.) Plaintiffs' argument that Spero's September and October 2020 public offerings establish scienter also fails, as these corporate offerings were made well before the March 2022 to May 2022 period. (Pls.' Opp'n at 27.) *Cf. In re Silvercorp Metals Inc. Sec. Litig.*, 26 F. Supp. 3d 266, 275–77 (S.D.N.Y. 2014) (noting that "motive alleged may have been strong enough to survive dismissal on its own because the stock offering . . . was temporally connected with the allegedly fraudulent SEC reports in the several quarters preceding it.").

Finally, as to the alleged government windfall payments, Plaintiffs fail to establish any circumstances where Defendants made misstatements or omissions to obtain funding. Plaintiffs' citation to *Beach v. Healthways, Inc.*, No. 3:08-cv-0569, 2009 WL 650408 (M.D. Tenn. Mar. 9, 2009) is confounding. There, the defendants were alleged to have made misstatements concerning their compliance with certain savings targets in a government contract and represented that they would be able to continue into a second phase of the contract even though it was unlikely. *Id.* at *2. Scienter was sufficiently pleaded because the plaintiff alleged "throughout the complaint, that the company and its senior executives had actual knowledge of the alleged misrepresentations and omissions" made to secure to government contract. *Id.* at *5. *Healthways* is not instructive here, where Plaintiffs have not pleaded any misstatements or omissions that Defendants made regarding the Trial to secure government payments. Thus, Plaintiffs fail to establish that the government payments provided motivation for any alleged fraud.

As Plaintiffs fail to establish any connection between these transactions and payments and Defendants' purported awareness of the Trial's deficiencies, the Court does not find that Plaintiffs have sufficiently pleaded scienter through motive and opportunity.

3. Core Operations Theory

Plaintiffs' attempt to advance a "core operations" theory of scienter is also unavailing (*See* Pls.' Opp'n at 28.) Core operations theory allows the court to "infer that a company and its senior executives have knowledge of information concerning the core operations of a business, such as events affecting a significant source of revenue." *In re Aegean Marine Petro. Network, Inc. Sec. Litig.*, 529 F. Supp. 3d at 173–74 (quoting *Okla. Firefighters*, 367 F. Supp. 3d at 37). That inference, however, cannot do all the heavy lifting to plead a cogent theory of scienter. *See In re Plug Power, Inc. Sec. Litig.*, No. 21-CIV-2004, 2022 WL 4631892, at *18 (S.D.N.Y. Sept. 29, 2022) ("While courts within this Circuit have debated the viability of the doctrine, the majority approach treats it as additional evidence of scienter but not independently sufficient to show scienter."); *In re Wachovia Equity Sec. Litig.*, 753 F. Supp. 2d 326, 353 (S.D.N.Y.2011) (considering "'core operations' allegations to constitute supplementary but not independently sufficient means to plead scienter"). Plaintiffs argue that because the development THBr was a core part of Spero's business, the Individual Defendants, who were personally involved in the approval process, must have been aware of the alleged fraud. (Pls.' Opp'n at 28.) But, as the Court has already concluded that Plaintiffs failed to establish scienter based on recklessness or motive and opportunity, this argument fails as a matter of law. Indeed, the Court has already found, *supra* sections III.A.1–2, that there is no indication that Defendants were aware of a near certainty that the FDA would disapprove of the inclusion of gram-positive patients.

Accordingly, Plaintiffs' claims under the Exchange Act § 10(b) and Rule 10b-5 are dismissed.

B. Exchange Act Section 20(a)

Because the Court finds that Plaintiffs have failed to sufficiently plead scienter, the Court also dismisses Plaintiffs claims pursuant to § 20 of the Exchange Act. *In re Sanofi*, 87 F. Supp 3d at 527 ("If plaintiffs have not adequately alleged a primary violation, i.e., a viable claim under another provision of the Securities Act or Exchange Act, then the § 20(a) claims must be dismissed.").

IV. CONCLUSION

For the foregoing reasons, Defendants' motion to dismiss for failure to state a claim is GRANTED. Plaintiffs' complaint is dismissed in its entirety.

SO ORDERED.

Dated: October 28, 2024
Brooklyn, New York

/s/ LDH
LASHANN DEARCY HALL
United States District Judge